IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

3743 EFW

Applicant:

Y. FREEDLAND

Serial Number:

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or:

SPLIT-NUT PRECISION FASTENERS

Art Unit:

3743

Examiner:

Kathryn P. ODLAND

Hon. Commissioner of Patents P. O. Box 1450 Alexandria, VA 22313-1450

AMENDMENT

Sir:

In response to an Advisory Action mailed June 15, 2004, kindly amend the instant application as follows:

In the Claims:

Please amend the claims as follows:

64. (Currently Amended) A biologically stable orthopedic securing system adapted to secure at least one elongate element to a tissue, the system comprising two or more nut sections that assemble to form a nut, the assembled nut comprising:

a nut surface adapted to substantially contact a tissue surface; one or more element channels extending substantially along the radial axis of at least one of the two or more nut sections, the one or more element channels adapted to press the at least one elongate element;

an outer surface defining a periphery of the nut sections; and a band disposed around the periphery.

79. (Currently Amended) A biologically stable orthopedic fastening system adapted to secure at least one elongate element to a tissue, the system comprising:

two or more nut sections that form a nut when assembled, the assembled nut comprising:

two or more inner surfaces adapted to clamp the at least one elongate element; an outer surface defining a periphery; and

a band that substantially surrounds the periphery, the height of the radial axis of the band being less than height of the radial axis of the nut.

94. (Currently Amended) A biologically stable orthopedic fastening system adapted to secure at least one elongate element to a tissue having a surface, the system comprising:

at least one first nut section having a first clamping surface adapted to clamp the at least one elongate element and a first compression surface adjoining the first clamping surface;

at least one second nut section having a second clamping surface adapted to clamp the at least one elongate element and a second compression surface adjoining the second clamping surface;

at least a portion of at least one of the first and second compression surfaces being compressed against the tissue surface while the first and second clamping surfaces clamp the at least one elongate element.

109. (Currently Amended) A biologically stable orthopedic fastening system adapted to secure at least one elongate element to a tissue having a surface, the system comprising two or more nut sections that form a nut when assembled, the assembled nut comprising:

two or more inner surfaces adapted to clamp the at least one elongate element; an outer surface defining a periphery of the nut sections;

- a compression surface adjoining the inner and outer surfaces, the compression surface being adapted to be juxtaposed against the tissue surface; and a band disposed around the periphery.
- 134. (Currently Amended) A method for securing a surface with biologically stable multiple sections radially arranged around an elongate element, the method comprising: extending a first portion of an elongate element from a surface; contacting the tissue with the multiple sections; and pressing the multiple sections around the at least one elongate element.
- 135. (Currently Amended) A method for securing a surface with a biologically stable nut

comprising two or more sections, the method comprising:

positioning the two or more nut sections around an elongate element extending from a surface;

contacting the surface with the nut sections; and encircling the nut sections with a band.

Attached are amendments in accordance with format requirements of the USPTO.

On page 23, following line 30, please add:

"FIG. 30' is a side view of a modified split nut and snap ring assembly being used as a suture nut. The halves of the split nut are separated;

FIG. 31' is a side view of the suture nut of FIG. 30', wherein the snap ring is engaged 10 more tightly with the split nut thereby forcing its halves together."

FIG. 32' is a bottom plan view of the assembly of FIG. 30'.

FIG. 33' is a bottom plan view of the assembly of FIG. 31'.

FIG. 34' is a cross-sectional perspective view of the snap ring of FIGS. 30'-33'.

FIGS. 35'-37' are perspective views of a suture nut in operation."

(PCT/IB00/00364, Page 9, lines 7-14)

On Page 48, following line 21, please add:

"The suture nut provides a very efficient method for applying compressive and fixating force by its button shape on the suture. The suture nut presses against the surrounding tissue surface. Since the suture nuts sections are fully cut longitudinally, they transmit the pressure of the encircling band relatively evenly along their entire length with their interface along the suture. As it is preferably made from relatively non-deforming bioabsorbable materials, the suture nuts sections transmit the full force of the encircling band to the suture, making the Suture Nut a strong fastener. The Suture Nut can be installed through small laparoscopic incisions and placed in small areas of the body using fine instrumentation. It saves operating room time as the Suture Nut installs much faster on the sutures than it takes to tie a knot in suture. Further, the Suture Nuts position against the tissue can be gauged much more precisely than suture knots.

"FIG. 30' depicts a suture nut assembly (58). The suture nut assembly comprises two

partial nut sections (58a, 58b) and a snap ring (60). The suture nut includes a bore (58c) that is generally not threaded. Moreover, the surfaces that define the bore (58c) at the inside of the suture nut are friction surfaces that are designed to grasp suture material.

"The suture nut is generally used as follows. The band (60) is engaged with the lower groove (59a) such that the sections (58a, 58b) are adjacent yet spaced from one another. A suture (61) is placed within the bore (58c) and the Suture Nut is slid along the suture until it sits against the tissue that is to be secured. The snap ring is slid from the lower groove (59a) to the upper groove (59b), thereby causing the sections (58a, 58b) to clamp the suture (61).

"FIGS. 35'-37' depict a suture nut as it is generally used to facilitate closure of an incision in a body tissue. A suture nut (58) is clamped onto a first end of the suture (61), which has a needle (63) at its second end. The needle and suture are threaded through the tissue adjacent an incision (62) in any manner used by a surgeon. The suture is pulled so that the suture nut abuts the tissue surface. The surgeon then continues to stitch the tissue to close the incision. Once the final stitch is made, the suture is tightened to close the incision and the second suture nut (64) is clamped onto the portion of the suture that is just exterior to the skin and is part of the last stitch. The suture is then cut to size, and the excess suture and attached needle are removed.

"In an alternate embodiment, the suture nut includes a single enlarged bore, or a pair of small bores, adapted to receive two suture ends. In this embodiment, a single suture nut can be used to grasp two different portions of a suture simultaneously. The paired holes can be separated as desired. Alternatively, the single enlarged hole can be oval or otherwise shaped to simultaneously accommodate two suture portions within it."

"The Suture Nut is preferably constructed from one or more of the combinations of polymers used in dissolvable implants, some of which were noted above, that can be made to dissolve more rapidly when in contact with a catalytic agent."

(PCT/IB00/00364, Page 17, line 7 to Page 18, line 27 and Page 6, lines 3-6)

Following Page 62 of Figures, please add pages labeled 11'/13' and 12'/13' from PCT/IB00/00364.

Please note that to distinguish between numbers in the incorporated Figs. and the instant patent Figs., a prime sign (') has been added to all numbers on the incorporated pages.